

Attorney Docket No. 01235-23625 Serial No.: 10/700,838

AMENDMENTS TO THE CLAIMS**RECEIVED
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1-34. (canceled)

35. (currently amended) A pharmaceutical composition comprising:

a therapeutically effective amount of cilostazol ;

a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprate, caprylic acid monoglycerides, caprylic acid diglycerides, and monoacetylated monoglycerides and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides, α -tocopherol, α -tocopherol acetate, α -tocopherol succinate, α -tocopherol polyethyleneglycol succinate, α -tocopherol polyethylene glycol 400 succinate, d1- α -tocopherol polyethyleneglycol 1000 succinate, and d- α -tocopherol polyethyleneglycol 1000 succinate; and

a release modulator which synchronizes the release of the cilostazol and the solubilizer, wherein the release modulator is selected from the group consisting of methyl cellulose, a hydroxypropyl methylcellulose derivative, hydroxypropyl methyl cellulose phthalate, hydroxymethylcellulose succinate, ethyl cellulose, an acrylic polymer, a polyvinylpyrrolidone copolymer, a polyvinyl acetyl phthalate, a high molecular weight polysaccharide gum, hydrogenated vegetable oil, glycerol dibehenate, glycerol dipalmitate, glycerol palmitostearate~~mono-stearate~~, glycerol distearate, α -tocopherol succinate, α -tocopherol polyethyleneglycol succinate, sucrose distearate, cetyl ester wax, and mixtures thereof;

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wherein the cilostazol is from 0.5% to 50% w/w of the composition ~~and at least 95 wt%~~
~~of the cilostazol is suspended in the composition~~, the solubilizer is present from 15% w/w to
95% w/w of the composition, the release modulator is from 1% to 50% w/w of the composition;
and wherein the composition is formulated to release the cilostazol is released over an extended
period of time, said extended period of time being between 2 and 24 hours.

36-41. (canceled)

42-46. (canceled)

47-50. (canceled)

51. (previously presented) The pharmaceutical composition of claim 35, wherein the release of
cilostazol and solubilizer are synchronized with a correlation coefficient of greater than 0.80.

52. (original) The pharmaceutical composition of claim 35 including one or more additives.

53. (canceled)

54. (original) The pharmaceutical composition of claim 35, wherein the solubilizer is d- α -
tocopherol polyethylene glycol 1000 succinate and the release modulator is α -tocopherol
succinate.

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55. (original) The pharmaceutical composition of claim 54 including one or more additives.

56. (original) The pharmaceutical composition of claim 55, wherein the solubilizer is d- α -tocopherol polyethylene glycol 1000 succinate, the release modulator is α -tocopherol succinate and the additive is polyethylene glycol.

57. (original) The pharmaceutical composition of claim 35, wherein the solubilizer is polyoxyl 40 hydrogenated castor oil and the release modulator is hydroxypropylmethylcellulose.

58. (original) The pharmaceutical composition of claim 35, wherein the solubilizer is polyoxyl 40 hydrogenated castor oil and the release modulator is glycerol dibehenate, glycerol palmitostearate, glycerol distearate, or mixtures thereof.

59. (currently amended) An oral dosage form comprising:

a therapeutically effective amount of cilostazol;

a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprate, caprylic acid monoglycerides, caprylic acid diglycerides, and monoacetylated monoglycerides and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides, α -tocopherol, α -tocopherol acetate, α -tocopherol succinate, α -tocopherol polyethyleneglycol succinate, α -tocopherol polyethylene glycol 400 succinate, d1- α -tocopherol polyethyleneglycol 1000 succinate, and d- α -tocopherol polyethyleneglycol 1000 succinate; and

a release modulator which synchronizes the release of the cilostazol and the solubilizer wherein the release modulator is selected from the group consisting of methyl cellulose, a

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~~hydroxypropyl methylcellulose derivative, hydroxypropyl methyl cellulose phthalate,~~
~~hydroxymethylcellulose succinate, ethyl cellulose,~~ an acrylic polymer, a polyvinylpyrrolidone
copolymer, a polyvinyl acetyl phthalate, a high molecular weight polysaccharide gum,
hydrogenated vegetable oil, glycerol dibehenate, glycerol ~~dipalmitate, glycerol~~
~~palmitostearate mono-stearate,~~ glycerol distearate, α -tocopherol succinate, α -tocopherol
polyethyleneglycol succinate, sucrose distearate, cetyl ester wax, and mixtures thereof;

wherein the cilostazol is from 0.5% to 50% w/w of the composition ~~and at least 95 wt%~~
~~of the cilostazol is suspended in the composition,~~ the solubilizer is present from 15% w/w to
95% w/w of the composition, the release modulator is from 1% to 50% w/w of the composition
and wherein the composition is formulated to release the cilostazol ~~is released~~ over an extended
period of time, said extended period of time being between 2 and 24 hours.

60. (currently amended) A solid oral dosage form comprising:

a therapeutically effective amount of cilostazol;

a solubilizer which synchronizes the release of the cilostazol and itself, said solubilizer
being selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8
caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan
monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl
mono/dioleate, glyceryl caprylate/caprate, caprylic acid monoglycerides, caprylic acid
diglycerides, and monoacetylated monoglycerides and diacetylated monoglycerides, linoleoyl
monoglycerides, lauroyl macrogol-32 glycerides, α -tocopherol, α -tocopherol acetate, α -
tocopherol succinate, α -tocopherol polyethyleneglycol succinate, α -tocopherol polyethylene
glycol 400 succinate, dl- α -tocopherol polyethyleneglycol 1000 succinate, and d- α -tocopherol
polyethyleneglycol 1000 succinate; and

a release modulator selected from the group consisting of methyl cellulose, a
~~hydroxypropyl methylcellulose derivative, hydroxypropyl methyl cellulose phthalate,~~
~~hydroxymethylcellulose succinate, ethyl cellulose,~~ an acrylic polymer, a polyvinylpyrrolidone
copolymer, a polyvinyl acetyl phthalate, a high molecular weight polysaccharide gum,
hydrogenated vegetable oil, glycerol dibehenate, glycerol ~~dipalmitate, glycerol~~

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~~palmitostearatemono-stearate~~, glycerol distearate, α -tocopherol succinate, α -tocopherol polyethyleneglycol succinate, sucrose distearate, cetyl ester wax, and mixtures thereof;

wherein the cilostazol is from 0.5% to 50% w/w of the composition ~~and at least 95 wt%~~
~~of the cilostazol is suspended in the composition~~, the solubilizer is present from 15% w/w to 95% w/w of the composition, the release modulator is from 1% to 50% w/w of the composition and wherein the composition is formulated to release the cilostazol ~~is released~~ over an extended period of time, said extended period of time being between 2 and 24 hours.

61. (original) The dosage form of claim 60, wherein the dosage form is a capsule.

62-64. (canceled)

65. (previously presented) The pharmaceutical composition of claim 35, wherein the release modulator is the same compound as the solubilizer.

66-74. (canceled)

75. (previously presented) The dosage form of claim 60, wherein the release of cilostazol and solubilizer are synchronized with a correlation coefficient of greater than 0.80.

76. (previously presented) The dosage form of claim 60, including one or more additives.

77. (previously presented) The dosage form of claim 60, wherein the solubilizer is d- α -

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tocopherol polyethylene glycol 1000 succinate and the release modulator is α -tocopherol succinate.

78. (previously presented) The dosage form of claim 77 including one or more additives.

79 (previously presented) The dosage form of claim 78, wherein the solubilizer is d- α -tocopherol polyethylene glycol 1000 succinate, the release modulator is α -tocopherol succinate and the additive is polyethylene glycol.

80. (previously presented) The dosage form of claim 60, wherein the solubilizer is polyoxyl 40 hydrogenated castor oil and the release modulator is hydroxypropylmethylcellulose.

81. (previously presented) The dosage form of claim 60, wherein the solubilizer is polyoxyl 40 hydrogenated castor oil and the release modulator is glycerol dibehenate, glycerol palmitostearate, glycerol distearate, or mixtures thereof.

82. (previously presented) The dosage form of claim 60, wherein the release modulator is the same compound as the solubilizer.